UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,489	12/15/2003	Xia Zhao	4133-031323 (P-6125)	3805

32182 7590 04/19/2006

DAVID W. HIGHET, VP AND CHIEF IP COUNSEL
BECTON DICKINSON AND COMPANY
[THE WEBB LAW FIRM]
FRANKLIN LAKES, NJ 07414-1880

EXAMINER	
CHORBAJI, MONZER R	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,489	ZHAO ET AL.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/30/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This final action is in response to the amendment received on 01/30/2006

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 8, 12-13, 16-18, 21-22, 24-25, 28-34, 36-38 42-43 and 46-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Kozimor et al (U.S.P.N. 6,231,936).

With respect to claims 1, 17 and 32, the Kozimor reference teaches a method for designing radiation stable (col.1, lines 7-10) prefilled syringes (col.8, lines 47-50 and col.4, lines 13-16) that is to be sterilized by gamma irradiation (col.2, lines 36-39, col.4, lines 10-15, col.10, lines 31-46 and col.9, lines 6-8). The prefilled syringes include polyolefin material and a radiation stabilizer (col.7, lines 14-17).

With respect to claims 2-3, 21-22, 33-34 and 36-37, the Kozimor reference discloses a therapeutic drug in a container (col.8, lines 47-49) for injection into the body where the container is a bag (col.8, lines 65-67) or a syringe (col.8, line 48).

With respect to claims 8,12-13, 25, 28-29, 38, 42-43 and 46-51, the Kozimor reference teaches a container manufactured from polypropylene (col.5, lines 43-44) that includes an additional polymer at, for example, 8 weight percent (col.4, lines 42-43).

With respect to claims 30-31, the Kozimor reference discloses a therapeutic drug in a container (col.8, lines 47-49) for injection into the body where the container is a bag (col.8, lines 65-67) or a syringe (col.8, line 48).

With respect to claims 16, 18 and 24, the Kozimor reference teaches irradiating with gamma radiation at doses of 2.5, 5.0, 7.5 (col.4, lines 23-27) and up to 10 Mrad (col.4, lines 22-23, for example, 10 Mrad is equal to 100 KGy) and also teaches irradiating prefilled syringes (col.8, lines 47-49) such that irradiating prefilled syringes necessarily means syringes that have already been sealed prior to irradiation step.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 6-7 and 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozimor et al (U.S.P.N. 6,231,936) as applied to claim 1 and further in view of the admitted state of the prior art.

With respect to claims 6-7 and 52-54, the Kozimor reference fails to teach placing medium irradiation limitations on ultraviolet absorbance at certain wavelength range value and on the concentration of hydrogen peroxide; however, the specification on page 2, lines 10-14, teaches that the required UV absorbance level is below 0.2 at 220-340 nm and the presence of hydrogen peroxide along with other oxidizing agents should be below 3.4ppm after the process of irradiation. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kozimor reference to include limits on UV absorbance value and on hydrogen peroxide value in order to comply with the European and/or U.S. Pharmacopoeia guidelines as taught in the specification (page 2, lines 1-14).

With respect to claim 55, the Kozimor reference teaches radiation stable (col.1, lines 7-10) prefilled container (col.8, lines 47-50 and col.4, lines 13-16) that is to be sterilized by gamma irradiation (col.2, lines 36-39, col.4, lines 10-15, col.10, lines 31-46 and col.9, lines 6-8) after being filled by a medium. The Kozimor reference fails to teach

placing medium range value on the concentration of oxidizable substances after the irradiation step; however, the specification on page 2, lines 10-14, teaches that the required UV absorbance level is below 0.2 at 220-340 nm and the presence of hydrogen peroxide along with other oxidizing agents should be below 3.4ppm after the process of irradiation. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kozimor reference to include limits on UV absorbance value and on hydrogen peroxide value in order to comply with the European and/or U.S. Pharmacopoeia guidelines as taught in the specification (page 2, lines 1-14).

7. Claims 4-5, 23 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozimor et al (U.S.P.N. 6,231,936) as applied to claims 2, 1, 17 and 32 respectively and further in view of Jacobs et al (Acta Pharm, IDS).

With respect to claims 4-5, 23 and 35, the Kozimor reference fails to teach saline water as the medium and the pH of the medium after irradiation between about 4.5 and about 7.0; however, the Jacobs reference teaches gamma irradiation of saline water (table 1) and, for example a pH of 5.0 for saline water after gamma irradiation (table 2). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kozimor reference to include irradiating saline water as taught by the Jacobs reference since saline water is used for injections (abstract).

8. Claims 9, 14-15, 26, 39 and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozimor et al (U.S.P.N. 6,231,936) as applied to claims 8, 25 and 38 and further in view of Williams et al (U.S.P.N. 4,994,552).

With respect to claims 9, 14-15, 26, 39 and 44-45, the Kozimor reference fails to teach the following: the composition of the container includes a clarifying agent such as dibenzylidene sorbitol alkyl thioether with a clarifying amount, a mobilizing additive such as a hydrocarbon oil and the stabilizer is bis (4-piperidinyl) diester of a dicarboxylic acid. The Williams reference teaches the following: the composition of the container includes a clarifying agent such as dibenzylidene sorbitol alkyl thioether with a clarifying amount (col.8, lines 45-47), a mobilizing additive such as a hydrocarbon oil (col.2, lines 43-44) and the stabilizer is bis (4-piperidinyl) diester of a dicarboxylic acid (col.4, lines 59-61). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kozimor reference by including a clarifying agent, a mobilizing additive and a stabilizer as taught by the Williams reference since they produce a polymeric composition of high clarity which may be radiation sterilized without degradation of its mechanical properties due to radiation (col.2, lines 30-32).

9. Claims 10-11, 27 and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozimor et al (U.S.P.N. 6,231,936) as applied to claims 8, 25 and 38 and further in view of Saito et al (U.S.P.N. 6,437,048).

With respect to claims 10-11, 27 and 40-41, the Kozimor reference fails to teach including a nucleating agent such as 2,2'-methylene-bis (4,6-di-t-butylphenol)

phosphate salt; however, the Saito reference, which is in the art of designing medical articles made of polyolefin material, teaches the use of aluminum 2,2'-methylene-bis (4,6-di-t-butylphenol) phosphate (col.29, lines 23-25). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kozimor reference by including a nucleating agent as shown by the Saito reference in order to ensure excellent glossiness and reflection of the obtained olefin article (col.28, lines 34-36).

10. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozimor et al (U.S.P.N. 6,231,936) as applied to claim 18 and further in view of Vellutato (U.S.P.N. 6,123,900).

With respect to claim 19, the Kozimor reference teaches that prefilled syringes containing a drug will be packaged for delivery (col.8, lines 47-48), but fails to explicitly teach irradiating packaged containers. The Vellutato reference teaches irradiating pharmaceutical compositions after being packaged inside a carton with gamma radiation (col.3, lines 1-9, col.4, lines 50-52 and col.5, lines 1-5). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Kozimor reference by gamma irradiating already packaged container as taught by the Vellutato reference since Gamma radiation has a high penetration capability (col.5, lines 22-26).

With respect to claim 20, the Kozimor reference teaches that the packaging includes blister packing (col.8, lines 19-20).

Response to Arguments

11. Applicant's arguments filed on 01/30/2006 have been fully considered but they are not persuasive.

On page 11 of the Remarks section, applicant argues that, "In contrast, Kozimor does not teach or suggest pre-filling a container with a medium prior to sterilizing the prefilled container with gamma irradiation." The examiner disagrees. See col.8, lines 47-50 or col.4, lines 13-16, lines 36-40, or col.8, lines 25-28. Clearly, the Kozimor reference teaches various embodiments where empty or prefilled containers can be irradiated with gamma radiation (col.9, lines 5-8).

On page 11 of the Remarks section, applicant argues that, "There is nothing in Kozimor to teach or suggest the claimed invention involving sterilization after filling or the syringe." The examiner disagrees. The Kozimor reference explicitly teaches that prefilled containers will undergo gamma irradiation sterilization step (See col.8, lines 47-50, col.4, lines 13-16, lines 36-40, col.8, lines 25-28, col.9, lines 5-8 and col.2, lines 38-41).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
04/16/2006

GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER